Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 312 be amended to read as follows:

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

1. The authority citation for 21 CFR part 312 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 371; 42 U.S.C. 262.

2. Section 312.42 is amended by revising paragraph (e) to read as follows:

§ 312.42 Clinical holds and requests for modification.

* * * * *

(e) *Resumption of clinical investigations.* An investigation may only resume after FDA (usually the Division Director, or the Director's designee, with responsibility for review of the IND) has notified the sponsor that the investigation may proceed. Resumption of the affected investigation(s) will be authorized when the sponsor corrects the deficiency(ies) previously cited or otherwise satisfies the agency that the investigation(s) can proceed. FDA may notify a sponsor of its determination regarding the clinical hold by telephone or other means of rapid communication. If a sponsor of an IND that has been placed on clinical hold requests in writing that the clinical hold be removed and submits a complete response to the issue(s) identified in the clinical hold order, FDA shall respond in writing to the sponsor within 30-calendar days of receipt of the request and the complete response. FDA's response will either remove or maintain the clinical hold, and will state the reasons for such determination. Notwithstanding the 30-calendar day response time, a sponsor may not proceed with a clinical trial on which a clinical hold has been imposed until the sponsor has been notified by FDA that the hold has been lifted.

* * * * *

Dated: December 4, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–33030 Filed 12–11–98; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–6200–4]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Notice of intent to delete the Whittaker Superfund Site from the National Priorities List; request for comments.

SUMMARY: The United States Environmental Protection Agency (U.S. EPA) Region V announces its intent to delete the Whittaker Site from the National Priorities List (NPL) and requests public comment on this action. The NPL constitutes Appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which U.S. EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) as amended. This action is being taken by U.S. EPA, because it has been determined that all Fund-financed responses under CERCLA have been implemented and U.S. EPA, in consultation with the State of Minnesota, has determined that no further response is appropriate. Moreover, U.S. EPA and the State have determined that remedial activities conducted at the Site to date have been protective of public health, welfare, and the environment.

DATES: Comments concerning the proposed deletion of the Site from the NPL may be submitted on or before January 13, 1999.

ADDRESSES: Comments may be mailed to Gladys Beard, Associate Remedial Project Manager, Superfund Division, U.S. EPA, Region V, 77 W. Jackson Blvd. (SR–6J), Chicago, IL 60604. Comprehensive information on the site is available at U.S. EPA's Region V office and at the local information repository located at: Minnesota Pollution Control Agency, 520 Lafayette Rd. North, St. Paul, Minnesota 55155–4194. Requests for comprehensive copies of documents should be directed formally to the Region V Docket Office. The address and phone number for the Regional Docket Officer is Jan Pfundheller (H–7J), U.S. EPA, Region V, 77 W. Jackson Blvd., Chicago, IL 60604, (312) 353–5821.

FOR FURTHER INFORMATION CONTACT: Gladys Beard, Associate Remedial Project Manager, Superfund Division (SR–6J), U.S. EPA, Region V, 77 W. Jackson Blvd., Chicago, IL 60604, (312) 886–7253 or Don de Blasio (P–19J), Office of Public Affairs, U.S. EPA, Region V, 77 W. Jackson Blvd., Chicago, IL 60604, (312) 886–4360.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. NPL Deletion Criteria
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I. Introduction

The U.S. Environmental Protection Agency (U.S. EPA) Region V announces its intent to delete the Whittaker Site from the National Priorities List (NPL), which constitutes Appendix B of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), and requests comments on the proposed deletion. The EPA identifies sites that appear to present a significant risk to public health, welfare, the environment, and maintains the NPL as the list of those sites. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund Response Trust Fund (Fund). Pursuant to § 300.425(e)(3) of the NCP, any site deleted from the NPL remains eligible for Fund-financed remedial actions if the conditions at the site warrant such action.

The U.S. EPA will accept comments on this proposal for thirty (30) days after publication of this document in the **Federal Register**.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses procedures that U.S. EPA is using for this action. Section IV discusses the history of this site and explains how the site meets the deletion criteria.

Deletion of sites from the NPL does not itself create, alter, or revoke any individual's rights or obligations. Furthermore, deletion from the NPL does not in any way alter U.S. EPA's right to take enforcement actions, as appropriate. The NPL is designed primarily for informational purposes and to assist in Agency management.

II. NPL Deletion Criteria

The NCP establishes the criteria the Agency uses to delete sites from the NPL. In accordance with 40 CFR 300.425(e), sites may be deleted from the NPL where no further response is appropriate. In making this determination, U.S. EPA will consider, in consultation with the State, whether any of the following criteria have been met:

(i) Responsible parties or other persons have implemented all appropriate response actions required; or

(ii) All appropriate non-time Critical Removal Actions or Fund-financed responses under CERCLA have been implemented, and no further response action by responsible parties is appropriate; or

(iii) The Remedial Investigation has shown that the release poses no significant threat to public health or the environment and, therefore, remedial measures are not appropriate.

III. Deletion Procedures

Upon determination that at least one of the criteria described in § 300.425(e) has been met, U.S. EPA may formally begin deletion procedures once the State has concurred. This **Federal Register** document, and a concurrent notice in the local newspaper in the vicinity of the Site, announce the initiation of a 30-day comment period. The public is asked to comment on U.S. EPA's intention to delete the Site from the NPL. All critical documents needed to evaluate U.S. EPA's decision are included in the information repository and the deletion docket.

Upon completion of the public comment period, if necessary, the U.S. EPA Regional Office will prepare a Responsiveness Summary to evaluate and address comments that were received. The public is welcome to contact the U.S. EPA Region V Office to obtain a copy of this responsiveness summary, if one is prepared. If U.S. EPA then determines the deletion from the NPL is appropriate, final notice of deletion will be published in the **Federal Register**.

IV. Basis for Intended Site Deletion

The Whittaker Site covers approximately 7.5 acres and is located in Hennepin County, Minnesota (5th Congressional District). The Whittaker Corporation acquired this Site from the American Petroleum Corporation in 1967. Whittaker operated the facility until 1980. The principal products produced at the Whittaker Site were industrial coatings and resins. Automotive product packaging was also a production activity which took place at this facility. One of the chemicals found in the storage tanks on-site was propylene glycol, commonly called antifreeze, which is thought to be one of the products packaged at this facility. Steel was also distributed from this facility. Chemicals were stored in approximately 28 aboveground tanks ranging in size from 2,000 to 200,000 gallons and 21 underground tanks ranging in size from 2,500 to 14,000 gallons. The tanks contained propylene glycol, styrene monomer, di-isobutyl ketone, methyl ethyl ketone, methyl isobutyl ketone, toluene, xylene, and other chemicals. A variety of wastes were generated as a result of the processes used at the Whittaker Site. These wastes included tank bottoms, paint sludge, old paints, off-specification paints and resins, and cleaning fluids.

On September 24, 1981, Minnesota Pollution Control Agency (MPCA) requested the Whittaker Corporation and Tool Tech Company to complete a Preliminary Remedial Investigation Phase I study. The Phase I report was submitted by Whittaker/Tool Tech Company to MPCA in January 1983. In response to a request from the MPCA, a groundwater investigation was initiated by the Whittaker Corporation in early 1983. Monitoring wells were installed as part of that groundwater investigation. Groundwater samples were analyzed and found to contain benzene, tetrahydrofuran, methyl isobutyl ketone, 1,1-dichloroethane, cis and trans 1,2-dichloroethylene and chlorobenzene, xylene, 1,1,2-trichloroethylene, cadmium, and chromium. The Whittaker Corporation completed site specific soil treatment and removal along with tank removal operations at the Whittaker Site in 1985.

Soil samples were collected/analyzed and ten monitoring wells were installed at the Site between 1983 and 1985. Specific response actions included during this period were:

- Removal of approximately 600 damaged drums and drum remnants with off-site disposal at a permitted Resource Conservation Recovery Act (RCRA) facility.
- Excavation of approximately 10,000 cubic yards of visibly contaminated soil.
- Physical separation of resins from soils resulting in the shipment of 12 truck loads of hazardous waste materials to an out-of-state permitted RCRA facility.
- Off-site incineration of 25 drums of recovered solvents.
- Excavation and thermal processing of soils on-site in an aggregate dryer.
- Landfarming of dried soils on-site to volatilize organics.
- Shipment of approximately 280 cubic yards of waste material off-site to a permitted RCRA facility.
- Installation of a groundwater pump and treat system using two air strippers in series.

A groundwater pump and treat system began operations on May 9,1985. The groundwater clean-up standards for the pump and treat system were based on the State issued Health Risk Limits (HRLs) for xylene, ethylbenzene, toluene and benzene.

The MPCA under state authority issued a Request for Response Action (RFRA) to the Whittaker Corporation on April 23, 1985. In response to the work completed at the Whittaker Site, the RFRA was amended on November 26, 1985. The amended RFRA requires Whittaker Corporation to perform the following actions under state authority:

1. Continue operation of the pump and ground water treatment system until specified groundwater clean-up levels are reached.

2. Continue monitoring the groundwater at and surrounding the Site for specific parameters listed in the amended RFRA. Submit written reports of the data collected to MPCA.

3. Initate a contingency plan in the event the system fails to achieve the groundwater clean-up levels.

4. Place notations on the property deed to notify purchasers of the existence of the amended RFRA and any resulting limitation on the use of the Whittaker Site, and

5. Follow the Site Closure plan spelled out in the RFRA.

The following are major submittals, approvals and actions taken by the Whittaker Corporation and the MPCA staff pursuant to the RFRA issued to the Whittaker Corporation on April 23, 1985, and as amended on November 26, 1985.

A Remedial Investigation Final Report (RI Final Report) was submitted by the Whittaker Corporation on June 14, 1985 and approved by the MPCA on July 5, 1985.

An Interim Response Action (IRA) Report was also submitted on June 14, 1985 and approved by the MPCA on July 5, 1985. The IRA report addressed the types and amounts of contaminated material removed from the Site; provided the hazardous waste manifests and shipping papers; described the follow-up restoration performed at the Site and adjacent property; provided details of areas excavated; described backfill techniques for backfill placed on the excavation; and provided an anticipated schedule for future Response Actions at the Site.

On July 30, 1985, the Whittaker Corporation submitted the following three reports:

1. An Alternatives Report.

2. A Detailed Analysis Report, and

3. A Response Action Implementation Report.

The MPCA approved all three reports on September 4, 1985.

The Alternatives Report evaluated various RA alternatives, the

effectiveness of each alternative, the feasibility of each alternative and a recommendation to implement or drop from consideration each alternative. The Detailed Analysis Report provided a detailed description of the recommended alternatives; an environmental assessment for each of the recommended alternatives, and, a conceptual design of the recommended combination of alternatives. And finally, the Response Action Implementation Report spelled out the selected remedy, the pump and treat system, and how that remedy would be installed and operated. The MPCA approved the Response Action Implementation Report with the modification of including future monitoring of 1,1-dichloroethylene and trichloroethylene in monitoring well number 10.

As required by the amended RFRA, the Whittaker Corporation installed a groundwater pump and treat system which ran from 1985 until July 11, 1994. The Whittaker Corporation alleged the pump and treat system was pulling contaminated groundwater into the system from off-site areas. Based on this assumption, Whittaker Corporation unilaterally shut the system down. It has not been in operation since July 11, 1994. The RFRA also required annual groundwater monitoring and submission of an annual report documenting work completed during the previous year. Whittaker Corporation has not submitted an annual monitoring report since 1995, in violation of the RFRA. As a result, the MPCA requested the Whittaker Corporation to perform additional soil and groundwater sampling.

The MPCA completed an investigation of two areas immediately adjacent to the Whittaker Site in 1997, one north and one west of the Whittaker Site. MPCA's goal was to evaluate whether either of these two adjacent areas could be causing groundwater to become contaminated and drawn into the Whittaker Site pump and treat system as the Whittaker Corporation alleged. MPCA did not find any evidence to support that theory.

On July 9, 1997, MPCA staff were present during excavations of soil on adjacent land west of the Whittaker Site. The field investigation performed adjacent to the Site was performed by 3K Paper Company, the owner of the property, in response to the MPCA Voluntary Investigation and Cleanup program. MPCA staff did not observe any substantial soil contamination during the time the trenching was being done by the 3K Paper Company consultant.

In 1997, MPCA staff reviewed reports and documentation supplied by Applied Coatings Technology, Inc., the company owning the property bordering to the north of the Whittaker Site. Based upon an evaluation of the data provided in these reports, MPCA determined that the soil or groundwater contamination from the Applied Coatings Technology, Inc. site was not likely to be contributing to the groundwater contamination at the Whittaker Site.

In May 1998, the Whittaker Corporation hired a consultant to investigate the possibility of any remaining soil contamination at the Whittaker Site and to investigate the possibility of any ground water contamination at and downgradient of the Whittaker Site. The field investigation found that soil and groundwater contamination at and down-gradient of the Whittaker Site remains, but are at levels which no longer pose a threat to public health or the environment.

The long-term effectiveness of the final remedy was demonstrated through the soil and groundwater investigation completed in May 1998. The data gathered during this investigation confirmed that the soils and groundwater on-site and downgradient of the Whittaker site do not pose a threat to public health and the environment for the present and future land-use classifications assigned to this site.

Long-term operation and maintenance of the Whittaker Site are also not necessary since the soils and groundwater meet the cleanup standards identified in the state issued RFRA. Two five-year reviews have been completed by MPCA and submitted to the U.S. EPA for approval. The last one was done December 31, 1997. Because it has been determined that no hazardous substances remain at the Site above health-based levels, a five-year review will no longer be conducted at this Site.

U.S EPA, with concurrence from the State of Minnesota, has determined that all appropriate Fund-financed responses under CERCLA at the Whittaker Superfund Site have been completed, and no further CERCLA response is appropriate in order to provide protection of human health and the environment. Therefore, U.S. EPA proposes to delete the Site from the NPL.

Dated: December 1, 1998

Steve Rothblatt,

Acting Regional Administrator, Region V.

[FR Doc. 98–32889 Filed 12–11–98; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 62

[CC Docket No. 98–185; FCC 98–294]

1998 Biennial Regulatory Review—Repeal of Part 62 of the Commission's Rules

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: As part of its 1998 biennial review of regulations pursuant to section 11 of the Communications Act of 1934, as amended (the Act),[1] the Commission initiated a Notice of Proposed Rule Making (NPRM) seeking comment on whether its rules governing interlocking directorates should be repealed. The Commission tentatively concludes that the rules should be repealed. The Commission also tentatively concludes that it should forbear from applying the provision of the Act that prohibits any person from holding the position of officer or director of more than one carrier subject to the Act without obtaining prior Commission authorization.

DATES: Comments must be received on or before December 14, 1998. Reply comments must be received on or before January 4, 1999.

ADDRESSES: Magalie Roman Salas, Office of the Secretary, Federal Communications Commission, 445 12th Street, S.W., Room TW–A325, Washington, D.C. 20554, with a copy to Jennifer Myers Kashatus of the Common Carrier Bureau, 2025 M Street, N.W., Room 6120, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Jennifer Myers Kashatus, Formal Complaints and Investigations Branch, Enforcement Division, Common Carrier Bureau (202) 418–0960.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's NPRM in CC Docket 98–195 [FCC 98–294], adopted on November 3, 1998, and released on November 17, 1998. The full text of the NPRM is available for inspection and copying during normal business hours in the FCC Reference Center, Room 239, 1919 M Street, N.W., Washington, D.C. The complete text of this decision also may be purchased from the Commission's duplicating contractor, International Transcription Services, 1231 20th Street, N.W., Washington, D.C. 20036.

[1] 47 U.S.C. 161.